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DeRoyal Industries, Inc.
Restraint Net

NOV 12 1996

510(k) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED

SUBMITTER INFORMATION

NAME:	DeRoyal Industries, Inc.	TELEPHONE:	(423) 938-7828
ADDRESS:	200 DeBusk Lane	CONTACT:	Camille Matlock
	Powell, TN 37849	DATE OF PREPARATION:	August 30, 1996

DEVICE NAMES

NAME:	DeRoyal Industries, Inc. Restraint Net
COMMON/USUAL NAME:	Restraint Net
CLASSIFICATION NAME (if known):	Restraint, Protective (80FMQ)

PREDICATE OR LEGALLY MARKETING DEVICES

J.T. Posey Company
DeRoyal Industries, Inc.

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Restraint Net is a protective restraint device that is intended for medical purposes to restrict patient body movements thereby enabling protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Restraint Net is designed similar to those marketed by other manufacturers. The Restraint Net is primarily comprised of white mesh.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Restraint Net is indicated for use, at the discretion of a responsible licensed healthcare professional, to restrict patient body movements thereby enabling protection of the patient or others. The Restraint Net/Bed is intended to be attached to a bed. The Restraint Net/Stretcher is intended to be attached to a stretcher.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of white mesh, white webbing straps (100% polyester), and steel nickel plated fasteners	Same
Size	Universal	Same
Vehicles for Attachment	Restraint Net/Bed: Bed Restraint Net/Stretcher: Stretcher	Same
Length of use	Short term use	Same
Level of Patient Activity	Highly Agitated or Disoriented Aggressive Patient requires physical control	Same